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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,704	02/05/2004	George C. Tsokos	Army 178	5604

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EXAMINER	
ASHEN, JON BENJAMIN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,704	TSOKOS ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5, 7, 10-11, 15 and 28, drawn to a method of treating systemic lupus erythematosus in a patient by administering T-cells that have been gene-modified *ex vivo* with antisense CREM , classified in class 424, subclass 93.21.

II. Claims 6, 8-9, 12-14, 16-17 and 27, drawn to an *ex vivo* method of modifying T-cells by administering antisense CREM, classifiable in class 435, subclass 461.

III. Claims 18-21, drawn to a method of treating systemic lupus erythematosus in a patient by administering T-cells that have been gene-modified *ex vivo* with TCR ζ chain, classified in class 424, subclass 93.21.

IV. Claims 22-25, drawn to an *ex vivo* method of modifying T-cells by administering a TCR ζ chain contained in a vector, classifiable in class 435, subclass 334.

V. Claims 4 and 26, drawn to a method of treating systemic lupus erythematosus in a patient by administering T-cells that have been gene-modified *ex vivo* with antisense CREM and TCR ζ chain, classifiable in class 435, subclass 465.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is drawn to a method of treating systemic lupus erythematosus in a patient by administering T-cells that have been gene-modified *ex vivo* with antisense CREM. Invention II is drawn to an *ex vivo* method of modifying T-cells by administering antisense CREM. Invention III is drawn to a method of treating systemic lupus erythematosus in a patient by administering T-cells that have been gene-modified *ex vivo* with TCR ζ chain. Invention IV is drawn to an *ex vivo* method of modifying T-cells by administering a TCR ζ chain contained in a vector. Invention V is drawn to a method of treating systemic lupus erythematosus in a patient by administering T-cells that have been gene-modified *ex vivo* with antisense CREM and TCR ζ chain.

In the instant case the different inventions not disclosed as capable of use together because each is a method that requires the administration of one of three distinct and of specifically modified t-cells (antisense, TCR ζ chain or both) wherein

each type of gene modified cell that is to be administered is not disclosed as administered with either of the other types. Each method is distinguished by a different modes of operation because each method comprises distinct method steps that are not required for the other methods. Moreover, each method will have a different function. The methods of Inventions I, III and V require administration of gene modified cells to patients wherein the steps required for modification are different between inventions. Invention I requires administration of antisense, can operate by simple transfection protocols and functions to inhibit the expression of CREM. Invention II requires administration of a vector that will express a polypeptide, is disclosed as requiring nucleoporation for transfection and functions to restore T-cell signaling. Invention V requires the administration of both antisense and a vector that will express a polypeptide, thereby operating by additional method steps not required for either of the previous two methods, and functions to inhibit the expression of CREM and restore T-cell signaling.

Inventions I, III and V are distinguished from Inventions II and IV because they operate by method steps that require administration of gene modified T-cells, to a patient. These steps and the considerations involved therein are not required to practice the methods of Inventions II and IV. Inventions II and IV are distinguished from each other because they have different functions and modes of operation. Each method comprises distinct method steps that are not required for the other methods. Invention II requires administration of antisense, can operate by simple transfection protocols and functions to inhibit the expression of CREM. Invention II requires

administration of a vector that will express a polypeptide, is disclosed as requiring nucleoporation for transfection and functions to restore T-cell signaling.

Furthermore, searching any of Inventions I-V together would impose a serious and undue burden. In the instant case, prior art searches of each method of making gene modified cells and each method of treatment comprising administering gene modified cells would not be coextensive. Search of each of these inventions would require different key word searches of the particular method steps required by each method that are not required by the other methods. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform a search and examination of any of Inventions I-V together.

3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and would require divergent searches of sequence and literature databases placing an undue administrative burden on the examiner, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba